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10/509,150	09/27/2004	Sung-Jin Kim	AP036-04	5035

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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,150	KIM, SUNG-JIN	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) *3-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 15 November 2007 with the amendment of claims 1 and 2.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 1-83 are currently pending.

This application contains claims 3-83 drawn to an invention nonelected with traverse in the reply filed on 8 November 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1 and 2 are currently under examination.

Claim Rejections - 35 USC § 112

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a subject promoter composition which may be applied to cosmetics, skin preparations, food and drinks comprising an extract of *Ophiopogon japonicus* root in an amount of 0.1 to 60 wt%, talc, lactose and magnesium stearate, does not reasonably provide enablement for a composition for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss; said composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to

500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*, *Ophiopogon japonicus*, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc, lactose, and magnesium stearate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Newly reapplied as necessitated by amendment.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: The claims are drawn to a composition for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss; said composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to 500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*, *Ophiopogon japonicus*, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc, lactose, and magnesium stearate.

Breadth of the Claims: The claims are broad in that a composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to 500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*, *Ophiopogon japonicus*, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc, lactose,

and magnesium stearatemay be administered to protect brain cells from excitotoxicity or improving memory of a patient suffering from memory loss. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples: The specification describes an undisclosed liriopsis extracted to provide fractions T, A, C, CM and M, which were used in an *in vitro* grease gap assay (Experimental Example 1), an extract of an undisclosed Liriopsis tuber (fraction T) was used in a $NaNO_2$ Memory Test an undisclosed XXX was used in a Passive Avoidance Test (Experimental Example 2), undisclosed Liriopsis tuber extracts (fractions T, A, C, CM and M) were used in Passive Avoidance Test (Experimental Example 3), undisclosed extracts of Liriopsis tuber (fractions T, A, C and M) were used in an ex vivo cholinesterase assay, to determine the effect of ERK I/II Activity and in studying the effect on the activity of insulin receptor (Experimental Examples 4, 5 and 6).

The specification envisions that a composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to 500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*, *Ophiopogon japonicus*, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc, lactose, and magnesium stearate will have utility in humans for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss.

However, no working examples are provided with regards to a composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to 500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*,

Ophiopogon japonicus, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc, lactose, and magnesium stearate having utility in humans for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss. Furthermore, no working examples are provided that demonstrate the efficacy of a composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to 500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*, *Ophiopogon japonicus*, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc, lactose, and magnesium stearate in humans for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable and underdeveloped. For example, Please note that the state of the art at the time the invention was made recognizes the combination of dwarf lily turf (*Ophiopogon japonicus*) and *Rehmannia glutinosa* in the form of a preparation of medicine for improving memory as taught by Wang et al., (N*, CN 1053370 C, Abstract only), however, the state of the art did not recognize a composition for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss; said composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to 500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*, *Ophiopogon japonicus*, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc. lactose and magnesium stearage, nor did the state of the art recognize for a composition for protecting brain cells comprising dwarf lily turf (*Ophiopogon japonicus*) and *Rehmannia glutinosa*. Applicant's specification specifically

discloses that there has not yet been a report on that a Liriopsis tuber extract has an effect on protecting brain cells and improving memory (See paragraph 0015 of the PreGrant publication).

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention.

Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose a composition for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss; said composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to 500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*, *Ophiopogon japonicus*, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc, lactose, and magnesium stearate. The Office further notes that while the specification discloses that the claim-designated methods and claim designated compositions will have utility in humans for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss, nowhere in the specification or in the limitations does Applicant direct the claimed subject matter to the administration of a composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to 500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*, *Ophiopogon japonicus*, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc, lactose, and magnesium stearate to any subject.

Amount of Experimentation Necessary: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to make and use composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to 500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*, *Ophiopogon japonicus*, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc, lactose, and magnesium stearate for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss. In order to carry out the claimed invention, one of ordinary skill in the art would have to identify a composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to 500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*, *Ophiopogon japonicus*, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc, lactose, and magnesium stearate that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claims 1 and 2 are not considered to be fully enabled by the instant specification.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

In the instant case, the original Claim 1 did not disclose protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss; said composition consisting essentially of an extract of Liriopsis tuber from about 5.0 to 500 mg, wherein said Liriopsis tuber is selected from the group consisting of *Liriope platyphylla*, *Ophiopogon japonicus*, *Ophiopogon stolonifer*, *Mondo japonicum*, and *Liriope spicata*, talc, lactose, and magnesium stearate, thereby introducing the limitations, "protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss", which is considered to be new matter. Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss. This is not sufficient support for the new genus: "protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss". This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new

references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hori et al. (O, JP 10-045616 A, Translation provided herein).

Hori teaches a subject promoter composition which may be applied to cosmetics, skin preparations, food and drinks comprising an extract of *Ophiopogon japonicus* root in an amount of 0.1 to 60 wt% (See abstract), which reads on an extract of Liriopsis tuber from about 5.0-500 mg (the range claimed by Applicant), talc (See paragraph 0028), milk sugar (See paragraph 0029), which is synonymous with lactose, and magnesium stearate (See paragraph 0043). Please note that although Hori does not teach the limitation, "consisting essentially of", Hori does teach that the composition may have one ingredient, from which an extract of *Ophiopogon japonicus* root, is an option and teaches other ingredients that may be added to the composition but that are not required.

Hori does not teach the exact combination of an extract of *Ophiopogon japonicus* root, talc, lactose, and magnesium stearate. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition taught by Hori to provide the instantly claimed invention by combining an extract of *Ophiopogon japonicus* root with talc, lactose, and magnesium stearate because at the time the invention was made, it was known at that it is possible to combine an extract of *Ophiopogon japonicus* root with talc, lactose, and magnesium stearate, as clearly taught by Hori, since Hori discloses that all of these ingredients may be used for the same purpose and as possible to add talc, lactose and magnesium

stearate to an extract of *Ophiopogon japonicus* root since these were all ingredients disclosed in Hori's specification as useful in the same composition.

Therefore, one would have been motivated to combine an extract of *Ophiopogon japonicus* root with talc, lactose, and magnesium stearate, because at the time the invention was made, the claimed ingredients were known in the art to be combinable and could be used in the same composition, as clearly taught by Hori.

Furthermore, one of ordinary skill in the art would have reasonable expectation of success in providing the instantly claimed product by combining the claimed ingredients of an extract of *Ophiopogon japonicus* root with talc, lactose, and magnesium stearate because the ingredients were known to be useful in the same composition, as taught by Hori.

Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a concentration of talc, lactose and magnesium stearate, and the concentration of the product and the percentage amounts of the ingredients thereof because talc, lactose and magnesium stearate are all known to be useful ingredients in making tablets and other edible compositions and are known to be combinable with an extract of *Ophiopogon japonicus* root. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

Although Hori does not teach his composition as a composition for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory

loss is intrinsic to the preparation taught by Hori because the ingredients and the amounts of the ingredients are taught by Hori are one and the same as disclosed in the instantly claimed invention of Applicant. Thus, a composition for protecting brain cells from excitotoxicity or improving memory of a patient suffering from memory loss is intrinsic to the composition taught by Hori.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Response to Arguments

Claim Rejections - 35 USC § 112

Applicant's arguments with respect to claims 1 and 2 have been considered but are moot in view of the new grounds of rejection.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
January 31, 2008

Terry McKelvey

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SUPERVISORY PATENT EXAMINER